

EXHIBIT A, PART 2

EXHIBIT 13

What to include on an ICR Report

- Provide the following details:
 - All applicable dates: date of report, procedure, date you were first notified.
 - Your contact information.
 - Physician/Hospital Information (name, address, etc.)
 - Patient Information (if available).
 - How the device was used.
 - Clear, concise event description (what happened before, during and after procedure).
 - Product Information and Serial/Lot numbers that were involved in the event.
 - If any information is not available or unknown, please indicated "N/A" or "UNK" in the appropriate field.

Your Responsibility

- To notify QA and forward ICR reports within two business days of becoming aware of complaint-Remember the clock starts ticking once you find out about the event!
- To obtain and provide accurate and complete information regarding all reports of alleged product deficiencies and adverse patient events.
- To request and obtain the actual device that was involved in the event for product evaluation.



INITIAL CONTACT REPORT

(Product Complaint Documentation)

FOR REFERENCE ONLY

Date: (month/date/year)

QA-Assigned ICR Number:

RMA Number:

PMI employee or Sales Representative completing form:

Hospital Involved:

Account #:

Address:

Telephone:

Person who encountered difficulty:

Title:

A. PATIENT INFORMATION:

Age at the time of event: or Date of Birth:

Sex: ☐ Female ☐ MaleWeight: lbs. Or kgs. Patient identifier? (if unchecked, presumed No) ☐ No ☐ Yes**B. ADVERSE EVENT/PRODUCT PROBLEM:**PROCEDURE Date:

Type:

and Indication:

*Date sales representative/PMI employee was first notified of event/problem:

• Problem as described to you (please be specific):

Current patient status?

• Did the difficulty result in any tissue damage or patient injury? (e.g. unanticipated tissue loss; unintended colostomy, resection or re-operation; unexpected/prolongation of hospitalization) ☐ No ☐ Yes (explain; be specific)

• If applicable, what was done to correct this condition? (be specific e.g. cautery, sutured, applied another device, etc.)

• Relevant tests/laboratory data, including dates:

• Other relevant history, including pre-existing medical conditions (e.g. Hepatic/Renal Dysfunction ☐; Diabetes ☐; Coagulopathy ☐; Prior Radiation Therapy ☐; Artherosclerotic Cardiovascular Disease ☐; etc.?)

• General attitude of medical practitioner regarding the patient status?

C. SUSPECT MEDICAL DEVICE:

Product (s) code:

Description (s):

Lot/Serial number (s):

How many surgically applied units did not meet expectations/How many units had the reported defect:

Will the device(s)/product(s) be sent back to PMI for evaluation ☐ No ☐ YesAre other samples being sent for evaluation? ☐ No ☐ Yes If yes, number of samples to be returned:

Other relevant devices/product(s) involved in the procedure (if any):

D. INITIAL REPORTER:

Who informed the sales representative or PMI employee of the event?

Occupation:

Address:

Phone:

Is a response required? ☐ No ☐ Yes, written response required to: (First name, last name, title)

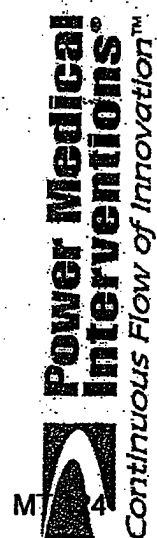
Please fill out completely using the following codes (if necessary): UNK= Unknown. N/A= Not Applicable

MT 123

Form F-00044, Rev. C

VICTORIA
ALLISON

Quality Systems



Agenda

1. PMI Quality System

Vicki Simon - 267-847-775 - 8156

2. Review of QSR's

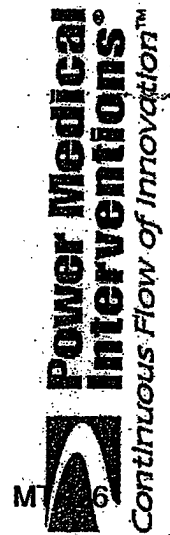
Vicki Simon

3. Review of Complaint Handling

Allyson Junod

Quality Assurance

All the systems that a company
puts in place to assure its
products and services meet
customer expectations.



Quality Assurance Department

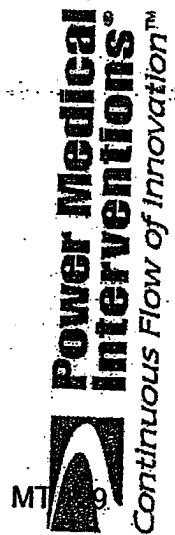
The Quality Assurance Department provides to all interested parties the documented evidence that the quality systems are functioning properly. The documented evidence is provided by testing, trending, auditing, etc.

The Quality Assurance Department is not the conscience of the company.

1. Operates in a Regulated Industry
2. Is an FDA registered Medical Device Manufacturer
3. Adheres to the Quality System Regulation (QSR's)
4. Is ISO 9001:2000 and ISO 13485:2003 certified
5. Has a Quality Policy

PMI is inspected by FDA, audited by our Registrar, has been audited by potential financial backers and undergoes internal self audits.

This also includes the Sales organization!



PMI Quality Documents

PMI Quality Documents are controlled documents that can be accessed through MasterControl™, PMI's electronic document control system.

System Administrator is Marissa Fleck if you are in need of assistance.

PMI Quality Documents

1. Quality Manual: 12-000001
2. Quality Policy: QP-000001
3. Management of Customer Complaints: SOP-00011
4. Medical Device Reporting: SOP-00037

MasterControl also has as controlled copies of all Labeling (IFU's, Operator's Manual, Product labels)

PMI's Product Complaint Process



Overview

- The Law
- Compliance with the Law
- Key Definitions
- Adverse Event Reporting
- Who to Contact

The Law

FDA Regulations

- FDA mandates the need for a formal complaint handling process (21 CFR 820) IN: 2 DAYS
- FDA must be made aware of ANY complaints that involve safety issues or actual adverse patient events (21 CFR 803) {Medical Device Reporting}
- Medical Device GMP (21 CFR 820 subpart 198)
 - Each manufacturer shall maintain complaint files. Each manufacturer shall establish and maintain procedures for receiving, reviewing and evaluating complaints by a formally designated unit.

The Law FDA Regulations

- Procedures shall ensure that:
 - ✓ All complaints are processed in a uniform and timely manner.
 - ✓ Oral complaints are documented upon receipt.
 - ✓ Complaints are evaluated to determine whether the complaint represents an event which is required to be reported to the FDA.

Product Complaints and Adverse Event Reports are LEGAL requirements. Every PMI employee has a role.

By Complying with the Law, we:

- Maintain PMI's financial vitality.
- Continue the company growth.
- No late ICR report submissions = No late MDR submissions = No FDA Observations.
- Prevent loss of market share.
- Reduce market risks.
- Reduce legal liabilities.
- Provide Customer Satisfaction.
 - Responsiveness to customer.
 - Drives Corrective Action.
 - Propels product enhancement.

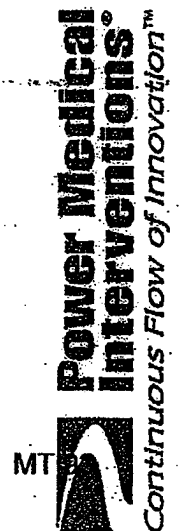
Definition

Complaint: Any written, electronic or oral communication that alleges deficiencies related to the:

- Identity
- Quality
- Durability
- Reliability
- Safety
- Effectiveness
- Performance

of any PMI product after it is released for distribution

Product Returns/RMA's



PMI's Return Policy

(overstocking)

DLUS – Full boxes only of disposable products may be returned within 60-days of the original purchase date and will be assessed a 20% restocking fee. Disposable product 'eaches' and/or product beyond 60-days of purchase cannot be returned.

MT



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Interventions®**

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PMI's Return Policy

Equipment – It is the customer's responsibility to maintain this equipment in proper working condition and the customer will be liable for any repairs not covered under the manufacturer's limited warranty. Equipment warranty is one (1) year from the date of shipment. [Full terms and conditions found in OPMA]

PMI's Return Policy

***Each part has a serial/part
ID and is assigned!***

***You are responsible and
held accountable for your
system/product!***

Return Procedure/RMAs

- ✓ Call Customer Service with notification of Return and obtain RMA No.
- ✓ Initial Contact Report (ICR) needs to be completed if a complaint (default in a clinical case) within 24 hours.

Return Procedure/RMAs

- ✓ Return of Product > Credit or Repair
 - Used product must be returned in Biohazard Packaging (replaced automatically when used)
 - Package is be clearly marked "Used healthcare product"
 - Repair cost may be involved
- ✓ Replacement or repaired product is sent to Sales Associate for delivery to customer

MT

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EXHIBIT 16

Esposito, Rita

From: Chase, Robert
Sent: Monday, November 01, 2004 10:58 AM
To: Tantiado, Myrick
Cc: Mintun, Keith; Esposito, Rita; Convery, Kevin
Subject: 60 Day Performance review

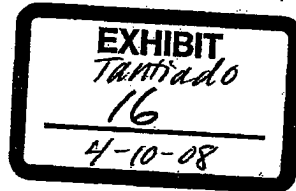
Myrick,

Please see the attached 60 Day performance review letter.

Rob Chase
General Manager
Power Medical Interventions
email: rchase@pmi2.com
Ph: 415-793-5197



Tantiado Perf
Review Ltr 1104....



MT 235



November 1, 2004

To: Myrick Tantiado
From: Rob Chase
Subject: Sixty day performance review
Cc: Kevin Convery, Keith Mintun, Rita Esposito

Dear Myrick,

This letter is to inform you that your performance over the past two months (Sept-Oct, 2004) ranks you as one of the top performing Sales Associates for PMI. Thank you for taking a leadership position in contributing to the company's success.

Our goal is still an aggressive one and I'm sure that you will continue to raise your own performance standard and continue to increase your revenue production each month.

PMI and I will continue to support your selling efforts. Call on me when needed to assist with your action plans.

We all look forward to your strong start leading to continued territory successes. When you succeed, we all succeed.

Regards,

Rob Chase

MT 234

EXHIBIT 18



**Power Medical
Interventions®**

The Ultimate Medical Technology™

Regional

**Sales Representative of the Year
2004**

**Myrick Tantiado
California Region**



**Power Medical
Interventions®**

EXHIBIT

Tantiado

18

4-10-08

EXHIBIT 19



**Power Medical
Interventions®**

2021 Cabot Boulevard Langhorne, PA 19047
Phone: 1-866-POWERMED
Fax: 267-775-8122

March 24, 2006

Myrick Tantiado
233 Winding Way
San Francisco, CA 94112

Dear Myrick:

Congratulations on your promotion to Regional Manager for the Bay Area territory, commencing on February 13, 2006. You will report to John Roache, Vice President of Sales.

You shall be paid on a salary basis at an annual rate of \$75,000, to be paid bi-weekly. In addition, you are eligible to participate in our monthly commission plan. The commission will be paid monthly at 5% commission on all regional sales generated from the previous month. The Company reserves the right to periodically reassess the commission percentage. As a member of the field sales selling organization you will also receive a monthly car allowance of \$600.00 to apply to car and insurance expenses.

As Regional Manager your responsibilities include but are not limited to:

1. Exceeding quota objectives that are in alignment with the PMI Mission, Purpose and Core Values.
2. Developing a business plan with metrics that are aligned with your Region's goals.
3. Hiring qualified candidates to fill open Sales Associate or Senior Sales Associate positions.
4. Coaching and managing your staff's performance.

Further, it is our intention to recommend to the Board of Directors that you be granted a stock option grant in the amount of 5,000 shares to vest in accordance with the 2004 Stock Option Plan.

Your employment at all times will be at will, meaning you are not being offered employment for a definite period and that either you or PMI may terminate the employment relationship at any time for any reason.

Thank you for your continued efforts and best of luck in your new position as Regional Manager.

Sincerely,

Accepted by:

Rita Esposito
Director, Human Resources

Myrick Tantiado _____ Date _____



MT 216

EXHIBIT 20



2021 Cabot Boulevard Langhorne, PA 19047
Phone: 1-866-POWERMED
Fax: 267-775-8122

March 24, 2006

Myrick Tantiado
233 Winding Way
San Francisco, CA 94112

Dear Myrick:

Congratulations on your promotion to Regional Manager for the Bay Area territory, commencing on February 13, 2006. You will report to John Roache, Vice President of Sales.

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Your employment at all times will be at will, meaning you are not being offered employment for a definite period and that either you or PMI may terminate the employment relationship at any time for any reason.

Thank you for your continued efforts and best of luck in your new position as Regional Manager.

Sincerely,

Accepted by:

Rita Esposito
Director, Human Resources

Myrick Tantiado _____ Date _____



MT 216

EXHIBIT 23

From: Chase, Robert
Sent: Saturday, June 17, 2006 11:19 AM
To: Tantiado, Myrick
Subject: Sales for the month

Myrick,

I hope all is well. Just wanted to make sure you get to 20K for the month. Marin should bring 5k then you need another 15K from the other targets we discussed. It's critically important that you get to 20k for the month as we discussed on the phone. I will call you when I get back in town but have a great next week.

Rob.

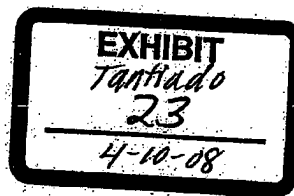


EXHIBIT 24



2021 Cabot Boulevard Langhorne, PA 19047
Phone: 1-866-POWERMED
Fax: 267-775-8197

July 10, 2006

Mr. Myrick Tantiado
233 Winding Way
San Francisco, C 94112

PERSONAL & CONFIDENTIAL

Dear Myrick:

Your employment is being terminated effective today, July 10, 2006. You will be paid your base salary and car allowance through July 10, 2006. Should you accept the terms of this letter, the company agrees to pay you a severance pay which will include ten (10) days base pay in lieu of notice. Any commissions earned during the months of June and July will also be paid to you on regularly scheduled commission pay dates. PMI will pay you for any accrued, unused vacation days. Once all outstanding company property has been received in Langhorne, PMI will issue any payments that are due.

Your health and dental insurance will end on July 30, 2006. A COBRA letter reviewing specific details of your medical and dental insurance benefit continuation will be mailed to your home by in the next couple of weeks. All other benefits will end on July 10, 2006.

Please return all Company property as outlined in the forthcoming letter no later than July 20, 2006. Please take the equipment to a Mailboxes Etc. store near you and have them properly package and ship the equipment back to PMI at 2021 Cabot Blvd. West, Langhorne, PA 19047. Please include the assigned RMA number when returning your equipment.

You are reminded of the Non-disclosure policy contained in Section 112 of the employee handbook, which you acknowledged receipt of upon hire. You are also reminded of the confidentiality agreement, which you signed when you joined the company. This agreement remains in effect and as such, you are not at liberty to divulge any company proprietary or confidential information to anyone outside Power Medical Interventions. You must make every effort to maintain and protect the reputation of Power Medical Interventions and that of their products, directors, officers and employees. You further agree that you will not disparage PMI or their products, directors, officers and employees or engage in any activities that reasonably could be anticipated to harm their reputation, operations, or relationships with current or prospective customers, suppliers or employees.



MT 218

I wish to take this opportunity to express our appreciation for helping to move the company forward and wish you every success in your future endeavors.

Should you have any questions or concerns please do not hesitate to contact me at 267-775-8119.

Please sign and fax this letter back to me at 267-775-8197.

Very truly yours,

Rita Esposito

Rita Esposito
Director, Human Resources

Received by:

Myrick Tantiado

Date: _____

EXHIBIT 30

From: Tantiado, Myrick
Sent: Wednesday, May 17, 2006 1:48 PM
To: Diehlman, Robin
Cc: Singh, Noel; Leonard, Brian D.
Subject: RE: SurgAssist Product Return

Importance: High

Robin,

Thank you for your email. I will contact Noel to help process the SurgAssist product return today.

Sincerely,

Myrick Tantiado
Power Medical Interventions
(415) 596-3405 Cell
(415) 349-8444 Fax

-----Original Message-----

From: Diehlman, Robin [mailto:Robin.Diehlman@ucsfmedctr.org]
Sent: Fri 5/12/2006 8:43 PM
To: Tantiado, Myrick
Cc: Singh, Noel; Leonard, Brian D.
Subject: SurgAssist Product Return

Hi Myrick,

Noel has made multiple attempts to coordinate product information with you so that we can prepare our SurgAssist product return.

Could you please coordinate this with him at your earliest convenience?

Thank you,
Robin

Robin Diehlman
OR Materials
415-353-1884 v.m.
415-353-8559 fax
robin.diehlman@ucsfmedctr.org

UCSF Medical Center
505 Parnassus Avenue, M61F, Box 0200
San Francisco, CA 94143

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MT 202

EXHIBIT 31



**Power Medical
Interventions®**

2021 Cabot Boulevard West Langhorne, PA 19047 Pfx: 1-866-POWERMED Fax: 267-775-8122 www.pmi2.com

August 18, 2006

Mr. Myrick Tantiado
233 Winding Way
San Francisco, CA 94112

Dear Myrick:

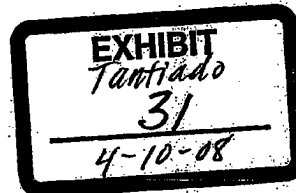
I am writing concerning the issue of product returns (and related refunds) from one of your accounts, University California – San Francisco. As you are aware, it is Power Medical's policy that any sales commissions paid to its sales representatives are subject to offset if those same products are subsequently returned by customers. In this case, UCSF has returned merchandise for which a total credit of \$13,789.00 has been issued by PMI. This would equate to \$1,525.59 in forfeited commission, such amount is to be withheld from your final expense reimbursement payment. The remaining expense reimbursement will be paid to you in the amount of \$2,937.68, through PMI's next scheduled payroll on August 25, 2006.

You have claimed that since these actual goods were not received by PMI until after your departure that somehow you are exempt from the policy. In fact, discussions between you and this customer regarding the return of product began long before you left PMI's employ as the attached email correspondence between you and Robin Diehlman indicates. I hope this answers any questions you may have. Should you have any questions concerning the attached, please feel free to call.

Sincerely,

A handwritten signature in cursive script that reads "Rita Esposito".

Rita Esposito, PHR
Director, Human Resources



Continuous Flow of Innovation™

PMI 000001

From: Tantiado, Myrick
Sent: Wednesday, May 17, 2006 1:48 PM
To: Diehlman, Robin
Cc: Singh, Noel; Leonard, Brian D.
Subject: RE: SurgAssist Product Return

Importance: High

Robin,

Thank you for your email. I will contact Noel to help process the SurgAssist product return today.

Sincerely,

Myrick Tantiado
Power Medical Interventions
(415) 596-3405 Cell
(415) 349-8444 Fax

-----Original Message-----

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Subject: SurgAssist Product Return

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Could you please coordinate this with him at your earliest convenience?

Thank you,
Robin

Robin Diehlman
OR Materials
415-353-1884 v.m.
415-353-8559 fax
robin.diehlman@ucsfmedctr.org

UCSF Medical Center
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San Francisco, CA 94143

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SURGASSIST COMPUTER POWERED STAPLING SYSTEM

Product	Description	QTY RETURNED
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Surg 200	SurgAssist Computerized/Robotic Surgical System	
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Includes:

- (1) Single Driver Power Console
- (2) FlexShaft II (15mm Flexible Steering Shafts)
- (2) Remote Control Units
- (1) Mobile Cart
- (1) Program Memory Card
- (1) Manual Release for FlexShaft II, 15mm
- (1) Operator Manual
- (1) Power Cord

1
2
2
1
1
1
1
1

POWER MEDICAL RETURNS

[illegible]

PMI 000004

